

lipid and a nucleic acid polymer, wherein said non-cationic lipid is a polyethylene glycol-based polymer.

112 3. (amended) The method of claim 1, wherein the amount of non-cationic lipid is from 1 to 15% of the particles.

REMARKS

This is in response to the Office Action mailed October 3, 2002 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Claims 1-14 are pending in this application.

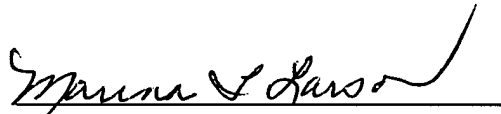
The Examiner rejected claim 3 under 35 USC § 112, second paragraph as indefinite. Claims 1 and 3 have been amended to correct the clerical errors which are the basis of this rejection and to clarify the terms in claim 1 to conform to claim 8 and the specification.

The Examiner rejected claims 1-6 and 8-13 as anticipated by Choi et al. Applicants respectfully traverse this rejection. As the Examiner correctly noted, the claims of the instant application are directed to a method for preventing particle aggregation or of making lipid:nucleic acid particle with less tendency to aggregate. The invention involves the addition of a lipid that includes a polyethylene-glycol based polymer to a composition containing pre-formed lipid:nucleic acid complexes. In contrast, the Choi reference discloses lipid particles in which PEG-modified ceramide lipids are combined with other lipids into lipid particles. There is no teaching in Choi of the order of addition recited in the present claims. Thus, there can be no anticipation of the claimed invention. Furthermore, nothing in Choi suggests that adding a PEG-modified ceramide to a pre-existing lipid:nucleic acid complex would result in any change in the aggregation behavior or any other specific property of that complex. Accordingly, Applicants submit that the rejection based on Choi should be withdrawn.

The Examiner also rejected claims 1-14 for obviousness-type double patenting over US Patent No. 5,981,501. Applicants enclose a terminal disclaimer and the appropriate fee to overcome this rejection.

In view of the foregoing, Applicants submit that the application, as amended, is in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully Submitted,

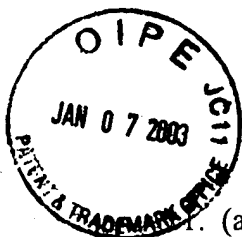
A handwritten signature in cursive script, reading "Marina T. Larson", is written over a horizontal line.

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MARKED UP COPY OF AMENDED CLAIMS

1. (amended) A method of preventing particle aggregation of lipid:nucleic acid complex particles, said method comprising the step of incorporating [an] a non-cationic lipid into a composition comprising lipid:nucleic acid complex particles, said particles comprising a cationic lipid and a nucleic acid polymer, wherein said [additional] non-cationic lipid is a polyethylene glycol-based polymer.

3. (amended) The method of claim 1, wherein the amount of [additional] non-cationic lipid is from 1 to 15% of the particles.

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